REMARKS

The foregoing amends claims 1, 16 and 19 and cancels claims 17, 32 and 37 without prejudice or disclaimer. Applicants respectfully request entry of these amendments and reconsideration of claims 1-16, 18-31, 33-36 and 40-60, in view of the following remarks.

Claim Amendments

Claims 1 and 19 are amended to recite either a tablet, comprising from 20 to 600 μg desmopressin acetate, or a method of making such a tablet, as previously recited in claims 17 and 37, respectively. Claim 16 is revised to make a clerical correction.

The amended claims recite embodiments prescribed previously, in claims that the Examiner has considered already. Thus, they should not require a further search or place any further burden on the Examiner. Applicants therefore respectfully urge the Examiner to enter these amendments after final.

The Examiner Interview

Applicants thanks Examiner Azpuru for the courtesies extended during the interview conducted on October 11, 2005, which was very helpful in advancing prosecution. Applicants' summary of the interview is set forth below.

The interview touched upon all of the issues raised in the pending Office Action. Applicants discussed the prior art rejection, and explained the lack of motivation to combine the cited references. Applicants also presented proposed claim amendments which were agreed to overcome the §112 rejection, and to further distinguish the claims over the cited references. As noted in the Interview Summary, it was agreed that the prior art rejection had been overcome. Applicants therefore believe that all issues raised in the Office Action have been obviated.

Prior Art Rejections

The claims were rejected for alleged obviousness in view of Staniforth and Petereit. As discussed during the interview, this combination of references does not teach or suggest the present invention.

As reflected in claim 1, the present invention provides a pharmaceutical composition as a tablet that comprises from 20 to 600 μg desmopressin acetate, together with a pharmaceutically acceptable excipient, diluent or carrier, or mixture thereof, and lubricant in an amount of from 0.05 to 0.40 percent by weight of the pharmaceutical composition. The invention also provides methodology for manufacturing such tablets, per claim 19, for example. No combination of Staniforth and Petereit suggests such a composition or method.

Staniforth is directed to dry powders for inhalation. Although Staniforth discloses that its inhaled powder formulations may comprise additives such as magnesium stearate, that information in no way teaches or suggests the present invention, which relates to desmopressin tablets. The Office Action cites Petereit for its disclosure of tablets, but there is no teaching of record that would had lead the skilled artisan to apply Staniforth's teachings on inhaled powder formulations to Petereit's coated tablets. Indeed, as discussed during the interview, those skilled in the art of pharmaceutical tablet manufacture would not look to inhaled powder formulations to solve problems associated with tablet manufacturing, such as the problems addressed by the present invention.

As taught in the specification, the present inventors found that desmopressin tablets comprising the recited amount of lubricant exhibited improved hardness without sacrificing compression speed, increasing machine wear, or sacrificing therapeutically relevant drug dissolution properties. *See, e.g.*, the specification at page 2. The person of ordinary skill would have had no reason whatsoever to expect that an additive used in an inhaled powder formulation would offer such benefits in the context of tablet manufacturing. Thus, there was no motivation to combine the references in the manner asserted in the Office Action.

During the interview, Applicants also explained that the dosage of desmopressin recited in the instant claims further distinguishes the invention. Neither Staniforth nor

Petereit teaches any specific desmopressin dosage. Moreover, the recited dosage (from 20 to 600 μg) is suitable for an orally administered tablet, but not for an inhaled powder. This is because desmopressin is extremely bioactive, and so only a very small amount is needed for therapeutic efficacy. When administered orally, most of the bioactivity (>99%) is lost as the peptide is degraded by the digestive system. Nevertheless, the remaining bioactivity is sufficient for therapeutic efficacy. If the same dose were administered as an inhaled powder, thereby bypassing the degradative effects of the digestive system, the physiological consequences of such a large bioactive dose could be harmful.

Thus, as agreed during the interview, the combination of Staniforth and Petereit does not teach or suggest the present invention. Applicants therefore respectfully urge that the §103 rejection be withdrawn.

Indefiniteness Rejection

Claim 32 was rejected for alleged indefiniteness. Applicants respectfully traverse this rejection for the reasons set forth in the response to the previous Office Action. Nevertheless, in order to expedite prosecution, Applicants have canceled claim 32 without prejudice or disclaimer, obviating this rejection.

Obviousness-Type Double Patenting

During the interview, the Examiner questioned whether the instant claims might be subject to obviousness-type double patenting rejections over co-pending applications 10/425,993 and 10/746,254. In order to expedite prosecution and obviate any such rejections, and without acquiescing or admitting to any obviousness-type double patenting, Applicants concurrently submit a terminal disclaimer over each of 10/425,993 and 10/746,254.

Information Disclosure Statement

Applicants are submitting herewith an Information Disclosure Statement to make of record references recently cited in co-pending application 10/746,254.

CONCLUSION

In view of the foregoing, Applicants believe that the application is in condition for allowance, and an early notice to that effect is earnestly solicited. Should there be any questions regarding this submission, or should any issues remain, Examiner Azpuru is invited to contact the undersigned by telephone in order to advance the prosecution.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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